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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/008,567      | 11/05/2001  | Douglas F. Covey     | WSHU 2044.1         | 6682             |

321 7590 05/05/2003

SENNIGER POWERS LEAVITT AND ROEDEL  
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16TH FLOOR  
ST LOUIS, MO 63102

| EXAMINER |
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HUANG, EVELYN MEI

| ART UNIT | PAPER NUMBER |
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1625

DATE MAILED: 05/05/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/008,567

Applicant(s)

COVEY, DOUGLAS F.

Examiner

Evelyn Huang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 36-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 36,37 and 39-47 is/are rejected.
- 7) ☒ Claim(s) 38 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. Claims 36-47 are pending. Claims 1-35 have been canceled according to the preliminary amendment filed on 4-7-2003.

### *Election/Restrictions*

2. In response to the restriction requirement, applicant has elected the invention of Group III, claims 36-38, directed to the compounds. Claims 1-35 of the non-elected inventions have been canceled.

### *Claim Rejections - 35 USC § 102*

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

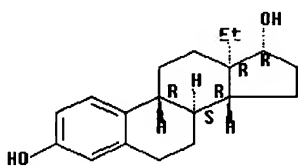
Although the following references do not specifically describe the cytoprotective activity in the compound as recited in the instant claims, such activity is intrinsic to the compound. While some of the prior art compounds do not have the same configuration as the instant, since it is well known in the art that there are only a limited possible configurations to a compound, one diastereomer would place the other diastereomers in the hands of the public. Furthermore, the base claim 36 as recited embraces all the diastereomeric configurations of formula I.

4. Claim 36 is rejected under 35 U.S.C. 102(b) as being anticipated by Romer I (Steroids, 1997, 62, pages 688-694, PTO-1449). In view of the disclosure that there may be more than one R<sup>z</sup> (page 14 of the specification) and the proviso referring to 'when the D ring is only substituted

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at carbon 17', the compounds, J843, J844, J72, J864, J897, J898 (page 690, Figure 1) are encompassed by the instant claim wherein  $R^z$  is substituted hydrocarbyl.

5. Claim 36 is rejected under 35 U.S.C. 102(b) as being anticipated by GB 1 298 587 (PTO-1449). The following compound (page 6, column 1, lines 36-40, procedure B) is encompassed by the instant claim.



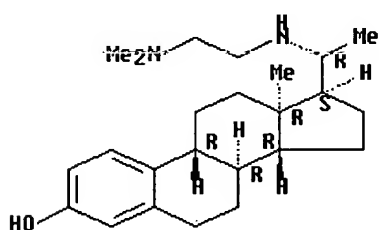
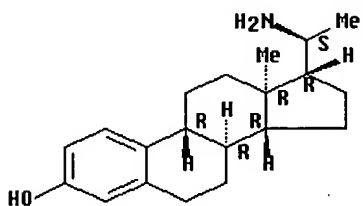
6. Claim 36 is rejected under 35 U.S.C. 102(b) as being anticipated by Tietze (Steroids, 1994, 59, pages 305-309, PTO-1449). In view of the disclosure that there may be more than one  $R^z$  (page 14 of the specification) and the proviso referring to 'when the D ring is only substituted at carbon 17', the compounds, 13 and 14 (page 308, scheme 2) are encompassed by the instant claim wherein  $R^z$  is an attached ring structure, such as cycloalkyl, attached directly there to, as a spiro ring (as defined and exemplified on pages 17, 20 of the specification).

7. Claim 36 is rejected under 35 U.S.C. 102(b) as being anticipated by Simpkins (WO 97/03661, PTO-1449). In view of the disclosure that there may be more than one  $R^z$  (page 14 of the specification) and the proviso referring to 'when the D ring is only substituted at carbon 17', the last two compounds in Table I wherein  $R=H$  (page 16/1) are encompassed by the instant claim.

8. Claim 36 is rejected under 35 U.S.C. 102(b) as being anticipated by Bonfils (5679668, PTO-1449). The following compounds are encompassed by the instant claim wherein  $R^z$  is substituted hydrocarbyl.

OK

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9. Claim 36 is rejected under 35 U.S.C. 102(b) as being anticipated by Romer II (Steroids, 1997, 62, pages 304-310, PTO-1449). In view of the disclosure that there may be more than one R<sup>z</sup> (page 14 of the specification) and the proviso referring to 'when the D ring is only substituted at carbon 17', the compounds, J 811, J835, J 861, J 851 (page 306, Figure 1) are encompassed by the instant claim wherein R<sup>z</sup> is an attached ring structure, such as cycloalkyl, attached directly there to, as a fused ring (as defined on page 17 of the specification). *ok*

10. Claims 36, 37, 39-44, 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Lunn (Tetrahedron, 1968, 24(23), pages 6773-6776, PTO-1449). Compound 5 in Scheme I is encompassed by the instant claims. *ok*

11. Claims 36, 37, 39-44, 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Gemmill (5552395, PTO-1449). Compounds II (column 6), VI (column 7), VII, VIII (column 8) are encompassed by the instant claims. *ok*

→ 103.

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***Claim Rejections - 35 USC § 102(a)***

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 36, 39-47 are rejected under 35 U.S.C. 102(a) as being anticipated by DE 199 17 930 (PTO-1449). The compounds of Beispiel 4 and 5 (page 11) are encompassed by the instant claims. ✓

***Claim Rejections - 35 USC § 112***

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 36, 37, 39-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In the definitions of  $R^z$ ,  $R^{13}$ , for the divalent 'amido', the substituent hanging therefrom is not described in the specification.

In the definitions of  $R^z$ , definitions for the 'heterocycloalkyl' and 'heterocycloalkenyl', and the substituents on these groups are not found in the specification.

*Maintain*

***Allowable Subject Matter***

14. Claim 38 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


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The compound of Tietze (Steroids, 1994, 59, pages 305-309, PTO-1449) or Romer II (Steroids, 1997, 62, pages 304-310, PTO-1449) has a 17-hydroxy which is absent in the instant. Motivation to modify the prior art compound to arrive at the instant is lacking.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 703-305-7247. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on 703-308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

  
Evelyn Huang  
Primary Examiner  
Art Unit 1625

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May 2, 2003